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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,329	12/14/2001	Thomas D. Intini	1901-14A	8122

7590

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EXAMINER

PICKETT, JOHN G

ART UNIT

PAPER NUMBER

3728

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/017,329

Applicant(s)

INTINI, THOMAS D.

Examiner

Greg Pickett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This Office Action acknowledges the applicant's Amendment A, presented as Paper No. 5. Claims 1-6 are pending in the application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification***

3. In light of the applicant's amendment, the objection to the specification is hereby withdrawn.

### ***Claim Objections***

4. In light of the applicant's amendment, the objection to claim 1 is hereby withdrawn.

### ***Claim Rejections - 35 USC § 112***

5. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said paper" in line 10. There is insufficient antecedent basis for this limitation in the claim. It is unclear as to whether the applicant is referring to a layer of paper or a reinforcing layer of paperboard material.

Claims 2-5 are dependent on claim 1 and are rejected for the above reasons.

***Claim Rejections - 35 USC § 103***

6. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerner (US 3,924,747) in view of Price (US 5,339,960).

Regarding claim 1, Gerner discloses a package (10) having a blister sheet (23) with blister pockets (19); a rupturable foil (25) sealed to the back of the blister sheet (as shown, Figure 8); and a reinforcing layer (27) adhered to the blister sheet-rupturable foil combination (as shown, Figures 1 and 8) with a portion (28) in registry with blister pockets (19) not adhered to the blister sheet-rupturable foil combination; and tear strips (28) formed in reinforcing layer (27) such that the reinforcing layer will delaminate (as shown, Figures 9-11).

Gerner meets all limitations claimed by the applicant except for a paper layer secured to the backside of the rupturable foil.

Price discloses a package (10) with backing layers (23) and (25) and a blister pack assembly (37, Figure 6). Blister pack assembly (37) is made of blister sheet (12), rupturable foil (60) and a layer of paper (62). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the package of Gerner with an additional paper layer as taught by Price in order to increase the force required to push the medicament through the rupturable foil layer, thereby precluding access by small children.

As to claim 2, the package of Gerner-Price discloses a plurality of blister pockets (Gerner, Figures 1-7) and a plurality of tear strips (Gerner 28).

As to claim 3, the package Gerner-Price discloses a blister sheet of polyvinyl chloride (Gerner Col. 3, ll. 12-14, Price Col. 4, ll. 37-41).

As to claim 4, the package of Gerner-Price discloses a paper layer of fifteen-pound paper (Price Col 4, ll. 59-60).

As to claim 5, the package of Gerner-Price discloses single dose medicament (Gerner 18).

Regarding claim 6, the package of Gerner-Price as applied to claim 1 above discloses the claimed method by presentation.

### ***Response to Arguments***

7. Applicant's arguments filed August 20, 2003 have been fully considered but they are not persuasive.

8. In response to the applicant's assertion that Gerner does not show delamination. Delamination is defined as separation into constituent layers. As is clearly shown in Figures 8-11, Gerner discloses delamination.

9. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention

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where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the suggestion to increase the force required to push the medicament through the rupturable foil layer can be found in Price (see for example, Col. 5, ll. 63-66).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Greg Pickett whose telephone number is 703-305-8321. The examiner can normally be reached on Mon-Fri, 9:30 AM to 6:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 703-308-2672. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

*GP*  
Gregory Pickett  
Examiner  
October 21, 2003



Mickey Yu  
Supervisory Patent Examiner  
Group 3700